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Sonnet BioTherapeutics Announces Positive Results from a Preclinical Combination Study of SON-1010 with anti-PD1 Checkpoint Inhibition

- ***Tumor volume growth inhibition improvements observed with the combination of SON-1010 (IL12-F_HAB) and a commercially available anti-PD1 antibody***
- ***Combination of SON-1010 with anti-PD1 increased survival rate***
- ***These data will guide future combination study designs with SON-1010 and checkpoint inhibitors***

PRINCETON, NJ / ACCESSWIRE / June 9, 2022 /Sonnet BioTherapeutics Holdings, Inc. (NASDAQ:SONN) ("Sonnet" or the "Company"), a biopharmaceutical company developing innovative targeted biologic drugs, today announced data from a preclinical combination study of SON-1010 with a commercially available anti-PD1 compound. These results suggest that dosing of SON-1010 (IL12- F_HAB) in combination with anti-PD1 demonstrated strong efficacy in the B16F10 mouse melanoma model, historically known as an immunologically insensitive model to anti-PD1.

Checkpoint inhibitors provide viable treatment alternatives to chemotherapy and/or radiation for patients with solid tumors, but there remains a robust need for more effective combination treatment regimens. With the objective of improving the checkpoint inhibitor response rate, Sonnet BioTherapeutics is developing a targeted approach using the company's Fully Human Albumin binding (F_HAB™) platform. The F_HAB technology targets tumor and lymphatic tissue, providing a mechanism for dose sparing and an opportunity to improve the safety and efficacy profile of not only Interleukin 12 (IL-12), but a variety of synergistic and potent immunomodulators. SON-1010 is currently undergoing Phase 1 clinical study in cancer patients and this preclinical study was designed to explore the combination potential with a checkpoint inhibitor (anti-PD1).

"We are excited to see that the combination of SON-1010 with an anti-PD1 antibody yielded compelling data in this preclinical model" said Pankaj Mohan, Ph.D., Sonnet Founder and Chief Executive Officer, and further added that, "These data support our strategy of pairing SON-1010 with a checkpoint inhibitor, with the goal of developing an improved treatment option for cancer patients."

Experimental Study Design: Three randomized cohorts of nine mice (n = 27), each with 150 mm^3 B16F10 melanoma tumors, were dosed with 3µg IL12-F_HAB and/or 10µg anti-PD1 antibody on days 0, 4 and 8 while the placebo cohort was not treated. Mean tumor volumes were measured every two or three days through an 18-day period.

Table 1: Mean Comparisons of Tumor Volume Growth Inhibition

Test Article	Mean Tumor Volume (mm^3) - Day 14	Tumor Growth Inhibition Ratios (% Inhibition)
Placebo (n = 9)	2260	-
Anti-PD1 antibody (n = 9)	2016	10.7%
Anti-PD1 + IL12-F_HAB (n = 9)	472	79.1%

Compared to the tumor-bearing placebo group at day 14, the treatment groups administered three doses of anti-PD1 antibody or three doses of the IL12-F_HAB + anti-PD1 antibody combination resulted in 10.7% and 79.1% tumor growth inhibition, respectively.

Survival data for study mice at 18 days further supports the efficacy synergy of IL12-F_HAB co-injected with anti-PD1 by improving the survival rate: (i) for anti-PD1 administration, only one mouse survived out of a total of nine, and (ii) for anti-PD1 + IL12-F_HAB administration, seven mice survived out of a total of nine. Additionally, the mice cohorts used in the preclinical efficacy study did not show any weight loss during the study in either the single agent or combination dosing arms.

"We are excited to have demonstrated these important data in an immunologically distinct animal model when IL12-F_HAB was dosed in combination with an anti-PD1 antibody," said John Cini, Ph.D., Sonnet's Chief Scientific Officer. "Further, this study evaluated the sequence of test article administration, whereby co-injection of IL12-F_HAB and anti-PD1 antibody was optimal when compared to administration of either anti-PD1 or IL12-F_HAB first. Targeting the tumor by linking IL-12 to an albumin-binding domain extends the cytokine half-life in the body, and we believe that is the key to inducing a successful local immune response in the tumor microenvironment."

About Sonnet BioTherapeutics Holdings, Inc.

Sonnet BioTherapeutics is an oncology-focused biotechnology company with a proprietary platform for innovating biologic drugs of single or bispecific action. Known as F_HAB (Fully Human Albumin Binding), the technology utilizes a fully human single chain antibody fragment (scFv) that binds to and "hitch-hikes" on human serum albumin (HSA) for transport to target tissues. F_HAB is the foundation of a modular, plug-and-play construct for potentiating a range of large molecule therapeutic classes, including cytokines, peptides, antibodies and vaccines.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential, "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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